

## **REMARKS**

Claims 1-75 and 77-82 were pending in the present application. Applicants note that the Office Action Summary (Paper No. 12) indicates that claims 1-84 are pending, however, this is incorrect. Applicants respectfully request that the proper number and count of claims be corrected. By virtue of this amendment, claim 78 has been cancelled, without prejudice, and claim 1 has been amended. Accordingly, claims 1-75, 77, and 79-82 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any subject matter of the claims as previously presented.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

### **Information Disclosure Statement(s)**

Applicants have noted that the Form PTO-1449 Information Disclosure Citation dated August 22, 2001 has been returned by the Office with only items 1-8 having been initialed.

Applicants are resubmitting a copy of the August 22, 2001 Form PTO-1449 and requesting the Examiner to consider each reference and properly initial each item and sign each page of the PTO-1449 in accordance with MPEP §609.

### **Rejections under 35 U.S.C. § 102(e)**

A. The Office rejected claims 1-5, 16-30, 32, 35-42, 66-68, 70-76, and 79-82 as allegedly being anticipated by Fleischman et al.

Applicants note that in the Office Action at p. 2, parag. 2, claim 42 is shown twice and claim 76 is also shown as being rejected by Fleischman et al. Applicants would like to point out that claim 76 has been previously withdrawn and is therefore improperly rejected.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union*

*Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (MPEP §2131.)

In response, claim 1 has been amended to recite an energy transfer element in which “at least one of said energy transfer elements is in electrical communication through said leg” of the expandable portion. (Specification, p. 28, line 10 - p. 29, line 4 & Figs. 5J-5L.) On the other hand, Fleischman et al. shows and describes a device where the electrodes are placed upon an electrically nonconductive insulator first disposed over the device. As further described, the rigid electrode elements 30 are arranged upon an “electrically nonconductive sleeve 32 which surrounds the underlying spline leg 22. The sleeve is made a polymeric, electrically nonconductive material ....” (Fleischman, 9: 12-15.) Other embodiments of Fleischman further describe the electrode rings as being placed upon the nonconductive sleeve 32. (Fleischman, 9: 18-21, 29-32 & Figs. 10-11B.)

Therefore, Fleischman cannot anticipate independent claim 1, as amended. The dependent claims 2-5, 16-30, 32, 35-42, 66-68, 70-75, and 79-82 ultimately depend from claim 1 and are patentable for at least the same reasons. Accordingly, Applicants respectfully request the reconsideration and withdrawal of the rejections of the claims under Fleischman et al.

**B.** The Office rejected claims 1-11, 14-19, 21-33, 38-40, 44, 45, 54-65, 70, 71, 74, and 79-82 as allegedly being anticipated by Jackson et al.

In response, claim 1 has been amended to recite “at least one discrete energy transfer element”. As described, the energy transfer element may transfer energy via an active region of the leg, i.e., a region discrete or specified along or through the leg(s).. (Specification, p. 23, lines 5-8; p. 28, line 13 - p. 29, line 10; see also Figs. 5J-5L.) However, Jackson specifically shows and describes a device which “comprises a wall peripherally enclosing an interior... An electrically conductive material is carried by the wall, forming an electrode region....” (Jackson, 2: 11-19.) Jackson further describes the device in which “the wall forming the body 22 carries an electrically conductive material that forms an electrode surface..., the electrically conductive

material comprises an electrically conductive shell 24 ....” (Jackson, 6: 13-18.) As further shown throughout the figures, the device is shown and described as having an electrically conductive surface over the region of the wall rather than having the electrodes discretely along or through the legs, as recited by claim 1.

Furthermore, the Office Action (Paper No. 12) at p. 2, parag. 5 states the following:

Applicants argue that Jackson et al. teach the use of an electrically insulating adhesive to bond the temperature sensor to the legs. The examiner must respectfully note this is merely one of the embodiments of Jackson et al. for while other embodiments such as that disclosed in the paragraphs bridging columns 24 and 25 of Jackson et al. example.

Applicants must respectfully disagree. As noted in the Office Action in the paragraphs bridging columns 24 and 25, Applicants submit that Jackson does describe an embodiment comprising a laminated structure 114 having at least a base layer 92 and an outer layer 98. However, Jackson further states that this structure is similar to that shown in Fig. 31 which goes on to show and describe “a base layer 92, formed from an electrically insulating material which peripherally surrounds the interior of the body 22 ... Each intermediate layer 94 is itself bounded by a layer 96 of electrically insulating material, so that the wires 26 are electrically insulated from each other. The laminate structure 90 also includes an outer layer 98 which is likewise formed from an electrically insulating material.” (Jackson, 23: 20-30 and Figs. 31 & 35.) Furthermore, with regards to Fig. 35 of Jackson, an electrically insulating material 120 is further applied over the thermocouple 112 (temperature sensing element) to electrically isolate the temperature sensor. (Jackson, 25: 10-15, Fig. 35.)

Therefore, Jackson describes a device where the temperature sensing element is actually electrically insulated and not a device in which the “temperature detecting element is in electrical communication with said leg”, as recited by claim 1. Thus, Jackson cannot anticipate claim 1. The dependent claims 2-11, 14-19, 21-33, 38-40, 44, 45, 54-65, 70, 71, 74, and 79-82 ultimately depend from claim 1 and are patentable for at least the same reasons. Accordingly, Applicants respectfully request the reconsideration and withdrawal of the rejections of the claims under Jackson et al.

**Rejections under 35 U.S.C. § 103(a)**

A. The Office rejected claims 34, 42, 43, 53, 68, 69, 72, 73 and 77 as allegedly being unpatentable over Jackson et al.

In support of the rejection, the Office Action (Paper No. 12) states the following on page 2:

Jackson et al. teach a device such as claimed specifically calling for sterilization, the visuazation system; electrically conductive paint; locating the temperature detector between the leg and the resistively heated element, forming the legs from a single sheet of stainless steel; and including an optical fiber and CCD. It would have been obvious to employ these measures since they are notorious in the medical arts official notice which has been taken; since they provide no unexpected result; and since they are not critical, thus producing a device such as claimed.

To establish a *prima facie* case of obviusness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143.

In response, dependent claims 34, 42, 43, 53, 68, 69, 72, 73 and 77 ultimately depend from independent claim 1 and are therefore patentable for at least the same reasons as claim 1 and Jackson, either alone or in combination with any other reference, necessarily fails to cure the defects of Jackson. Accordingly, Applicants respectfully request the reconsideration and withdrawal of the rejections of the claims under Jackson et al.

B. The Office rejected claim 78 as allegedly being unpatentable over Spears et al. in combination with Waksman et al.

In support of the rejection, the Office Action (Paper No. 12) states the following on pages 2-3:

Spears et al. teach the modification of a smooth muscle structure by dilation and heating to create a larger opening therein. Waksman et al. teaches the equivalence of smooth muscle cell treatment in various smooth muscle structures such as blood vessels and bronchi. It would have been obvious to the artisan of ordinary skill to employ the method of Spears, et al. on a constricted bronchi, since this is equivalent to a constricted blood vessel, as taught by Waksman et al., thus producing a modified lung such as claimed.

Claim 78 has been cancelled, without prejudice. Therefore, this rejection is moot.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under Spears et al. in combination with Waksman et al.

## CONCLUSION

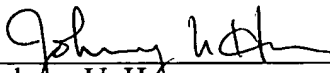
Applicants have, by way of the remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 435712000921.

Respectfully submitted,

Dated: November 21, 2002

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Claim 1 has been amended, as follows:

1. (Amended Twice) An energy transfer apparatus for facilitating energy transfer into a mass of airway tissue, said apparatus sized to enter a bronchus or bronchiole of a human lung and comprising:

a flexible elongated body having a proximal portion and a distal portion and at least one lumen extending therebetween;

a distally located expandable portion of said elongated body, said expandable portion comprising a plurality of legs and having a first state and a second state, wherein said second state is radially expanded from said elongated body;

a distal tip located distally of said [expandable portion] plurality of legs;

at least one discrete energy transfer element at an exterior of [said expandable portion] at least one of said legs such that at least one of said energy transfer elements is in electrical communication through said leg, wherein each of said energy transfer elements is configured to contact a wall of the bronchus or bronchiole when said [expandable portion] plurality of legs is in said second state,

a proximal joint at an intersection of said distal portion and said [expandable portion wherein said expandable portion comprises a] plurality of legs, each of said legs having a first end extending from said proximal joint and a second end terminating at a distal joint, said distal joint being adjacent to said distal tip;

[a] at least one temperature detecting element attached to at least one of said plurality of legs wherein said temperature detecting element is in electrical communication with said leg and wherein said leg is a continuous member; and

a deployment member configured to move said expandable portion between said first and second state, said deployment member extending at least between said expandable portion and said proximal portion of said elongated body.

Claim 78 has been cancelled, without prejudice.